1. (Amended) A medical device for attaching soft tissue to a bone comprising a bone anchor and a protective cover formed from a solid, non-hollow, non-inflatable mass of biocompatible material, wherein said bone anchor is substantially encapsulated in said mass.

6. (Amended) The protective cover of claim 1, further comprising an antimicrobial material.

19. (Amended) The method of claim 18, wherein said protective cover further comprises an antibiotic.

REMARKS

In the Final Office Action dated April 1, 2003, claims 1-10 were considered and pending claims 11-22 were withdrawn from further consideration as being drawn to a nonelected invention. The Final Office Action rejected claims 1-10 under 35 U.S.C § 102.

In the present Amendment, claim 1 is amended to more clearly claim Applicants' invention and claims 6 and 19 are amended to fix typographical errors. Claims 1-10 are presented for reconsideration. Applicants respectfully submit that no new matter is introduced by the present Amendment. Support for the present Amendment may be found at least at page 2, lines 23-27, and page 10, lines 14-17. In accordance with 37 C.F.R. § 1.121, a marked-up copy of the claims, and a clean copy of all pending claims, as amended herein, are attached.

Claim Rejections Under 35 U.S.C. § 102

The Final Office Action rejects claims 1, 2, 4-8, and 10 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,264,676 issued to Gellman *et al.* (hereinafter "Gellman *et al.*"). The Final Office Action rejects claims 1, 2, 4-7, and 9 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,048,050 issued to Draenert (hereinafter "Draenert"). The Final Office Action rejects claim 1 and 3-5 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,997,541 issued to Schenk. Applicants respectfully

traverse the § 102 rejections to the extent that they are maintained over amended independent claim 1 and claims depending therefrom.

Anticipation under 35 U.S.C. § 102 requires that each and every element as set forth in Applicants' claim be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (M.P.E.P. § 2131). In order to anticipate a claim, the identical invention must be shown in as complete detail as is contained in the patent claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (M.P.E.P. § 2131).

Applicants claim a medical device for attaching soft tissue to a bone. Applicants' medical device, as recited in independent claim 1, includes a bone anchor and a protective cover formed from a solid, non-hollow, non-inflatable mass of biocompatible material; the bone anchor is substantially encapsulated in the mass.

Applicants respectfully submit that Gellman *et al.* fails to teach or suggest the elements of claim 1. Specifically, Gellman *et al.* fails to teach or suggest a protective cover formed from a solid mass of biocompatible material that is not hollow and not inflatable. Instead, Gellman *et al.* teaches covering a bone anchor with a balloon 279 or a gelatin structure or caplet 290. See Gellman *et al.*, column 19, lines 62-67, column 20, lines 29-32, column 21, lines 20-31, and FIGS. 26a and 26b showing a hollow cover, 279 and 290, respectively, protecting a bone anchor. Applicants respectfully submit that balloons and/or gelatin caplets are hollow masses, which can be filled or inflated and are therefore not solid, non-hollow, non-inflatable masses. Thus, Applicants respectfully submit that Gellman *et al.* fails to disclose all of the elements of their claimed invention and request that the rejection of independent claim 1 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

Applicants respectfully submit that Draenert also fails to teach or suggest Applicants' claimed protective cover formed from a solid non-hollow, non-inflatable mass of biocompatible material. Rather, Draenert teaches an implant 10 having a form of a structured hollow cylinder with axis 12. See Draenert, column 7, lines 33-34 and FIG. 1.

Since Draenert teaches only hollow implants to cover a bone screw, Applicants respectfully submit that Draenert fails to teach or suggest a medical device including a protective cover formed from a solid, non-hollow, non-inflatable mass of biocompatible material. Applicants request that the rejection of independent claim 1 under 35 U.S.C. § 102(b) in view of Draenert be reconsidered and withdrawn.

Further, Applicants submit that Schenk fails to teach or suggest all of the elements of Applicants' claim 1. Specifically, Schenk, like Gellman *et al.* and Draenert, fails to teach or suggest a protective cover formed from a solid, non-hollow, non-inflatable mass of biocompatible material. Instead, Schneck teaches a hollow cylindrical body 2 that covers a bone screw. See Schenk, column 3, lines 49-53 and FIGS. 1 and 2. As discussed above, Applicants submit that a hollow cylindrical body or implant is not a solid, non-hollow, non-inflatable mass. Thus, Schenk, like Gellman *et al.* and Draenert, fails to teach a protective cover formed from a solid mass of biocompatible material.

Applicants also request that the 35 U.S.C. § 102 rejections of claims 2-10 be withdrawn. Claims 2-10 depend directly or indirectly from independent claim 1 and thus are patentable at least for all the reasons that claim 1 is patentable.

CONCLUSION

Applicant respectfully requests entry of this amendment and response, withdrawal of all bases of rejection, and allowance of claims 1-10 in due course. The Examiner is invited to telephone Applicants' under signed representative at (617) 248-7374 to discuss any outstanding issues.

Respectfully submitted,

Date: May 29, 2003
Reg. No.: 35,393
Tel. No.: (617) 248-7374
Fax No.: (617) 248-7100

Robert J. Tosti
Attorney for Applicant(s)
Testa, Hurwitz, & Thibeault, LLP
High Street Tower
125 High Street
Boston, MA 02110

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MARKED-UP COPY OF AMENDMENTS TO THE CLAIMS

Please amend claims 1, 6, and 19 as follows:

1. (Amended) A medical device for attaching soft tissue to a bone comprising a bone anchor and a protective cover formed from a solid, non-hollow, non-inflatable mass of biocompatible material, wherein said bone anchor is substantially encapsulated in said mass.

6. (Amended) The protective cover of claim[s] 1, further comprising an antimicrobial material.

19. (Amended) The method of claim[s] 18, wherein said protective cover further comprises an antibiotic.

CLEAN COPY OF ALL PENDING CLAIMS

1. A medical device for attaching soft tissue to a bone comprising a bone anchor and a protective cover formed from a solid, non-hollow, non-inflatable mass of biocompatible material, wherein said bone anchor is substantially encapsulated in said mass.

2. The protective cover of claim 1, wherein said mass is substantially deformable.

3. The protective cover of claim 1, wherein said mass is substantially brittle.

4. The protective cover of claim 1, wherein said mass comprises a bioabsorbable material.

5. The protective cover of claim 4, wherein said bioabsorbable material is selected from the group consisting of cross-linked alginated gel, cross-linked collagen, cross-linked hyaluronic acid hydrogel, polylactic-co-glycolic acid, polylactic acid, polyglycolic acid, polyurethane.

6. The protective cover of claim 1, further comprising an antimicrobial material.

7. The protective cover of claim 6, wherein said antimicrobial material comprises an antibiotic.

8. The protective cover of claim 7, wherein said antibiotic is selected from the group consisting of nafcillin, aminoglycoside, ciprofloxin, piperacillin/tazobactum, ampicillin/sulbactum, vancomycin, cephalosporin, TMP/SMX, ampicillin, gentamicin, tobramycin, and ciprofloxacin.

9. The protective cover of claim 8, wherein said antibiotic is disposed within a bioabsorbable material to form said protective cover.

10. The protective cover of claim 8, wherein said antibiotic is applied to at least one surface of said protective cover.

11. A method of inserting a bone anchor into a bone, comprising:

(a) providing a bone anchor;

(b) providing a protective cover adapted to encapsulate said bone anchor;

(c) encapsulating said bone anchor in said protective cover;

(d) locating a bone anchor implantation site on a bone; and

(e) causing said bone anchor to penetrate said protective cover and implant in said bone.

12. The method of claim 11, wherein said bone anchor is encapsulated in said protective cover prior to engagement of said bone anchor to an implantation device.

13. The method of claim 11, wherein said bone anchor is encapsulated in said protective cover after engagement of said bone anchor to an implantation device.

14. The method of claim 11, wherein said protective cover for encapsulating a bone anchor comprises a generally ellipsoidal mass.

15. The method of claim 14, wherein said mass is substantially deformable.

16. The method of claim 14, wherein said mass is substantially brittle.

17. The method of claim 14, wherein said mass comprises a bioabsorbable material.

18. The method of claim 17, wherein said bioabsorbable material is selected from the group consisting of cross-linked alginated gel, cross-linked collagen, cross-linked hyaluronic acid hydrogel, polylactic-co-glycolic acid, polylactic acid, polyglycolic acid, polyurethane.

19. The method of claim 18, wherein said protective cover further comprises an antibiotic.

20. The method of claim 19, wherein said antibiotic is selected from the group consisting of nafcillin, aminoglycoside, ciprofloxin, piperacillin/tazobactum, ampicillin/sulbactum, vancomycin, cephalosporin, TMP/SMX, ampicillin, gentamicin, tobramycin, and ciprofloxacin.

21. The method of claim 20, wherein said antibiotic is disposed within said bioabsorbable material to form said cover.

22. The method of claim 20, wherein said antibiotic is applied to at least one surface of said protective cover.